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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,808	12/21/2001	Clas Kallander	KALL3001/REF	4746

23364 7590 10/01/2003

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EXAMINER

WINKLER, ULRIKE

ART UNIT PAPER NUMBER

1648

DATE MAILED: 10/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/926,808

Applicant(s)

KALLANDER ET AL.

Examiner

Ulrike Winkler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 9-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 9-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/2/01 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1. 6) ☐ Other:

DETAILED ACTION

The Preliminary Amendment filed 21 December 2001 (Paper No. 1) is acknowledged and has been entered. Claims 5-8 have been cancelled. Claims 1-4 and 9-12 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, Paper No. 1, is attached to the instant Office Action.

Drawings

The drawings are objected to, please see Notice of Draftsperson's Review attached to the instant Office Action. Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is rejected because it is not clear if the claim requires a single selection from each of the groups listed or if the assay needs to have only a few of the components listed present in the kit to carry out the method. Clarification is required.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 9, 10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Shao et al. (Antiviral Chemistry and Chemotherapy, 1997; see IDS).

The instant invention is drawn to a kit comprising polyriboadenylic acid (prA) [a.k.a. poly (A); poly (rA); polyadenylate; polyadenosine] and/or polydeoxyadenylic acid (pdA) [a.k.a. oligo (dA); poly dAp; poly (dA)] bound to a solid surface, the kit further comprises RT-type assay components. The kit may also contain (does not require) a reference enzyme and a detection system.

For this office action, the product-by-process claims were interpreted as “a composition of matter” (which are *products*, wherein the chemical nature (prA or pdA bound to a solid surface) or materials used. Product-by-process claims are not limited to the manipulations of the recited steps, only to the structure implied by the steps. M.P.E.P. Section 2113 states that:

“[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the

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product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted)

Shao et al. disclose the use of a non-radioactive microtiter plate RT-assay in which the immobilized template polyriboadenylic acid (prA) is bound to the plate (see figure 1). Therefore, the instant invention is anticipated Shao et al.

Claims 1, 4 and 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Ekstand et al. (Biotechnology Applied Biochemistry, 1996; see IDS).

The instant invention is drawn to a kit comprising polyriboadenylic acid (prA) and/or polydeoxyadenylic acid (pdA) bound to a solid surface, the kit further comprises RT-type assay components. The kit may also contain (does not require) a reference enzyme and a detection system.

For this office action, the product-by-process claims were interpreted as “a composition of matter” (which are *products*, wherein the chemical nature (prA or pdA bound to a solid surface) or materials used. Product-by-process claims are not limited to the manipulations of the recited steps, only to the structure implied by the steps. See M.P.E.P. Section 2113.

Ekstand et al. disclose the use of a non-radioactive microtiter plate RT-assay in which the immobilized template polyriboadenylic acid (prA) is bound to the plate (see page 97, template binding and enzyme assay). Therefore, the instant invention is anticipated by Ekstand et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shao et al. (Antiviral Chemistry and Chemotherapy, 1997; see IDS), Ekstand et al. (Biotechnology Applied Biochemistry, 1996; see IDS), Suzuki et al. (Journal of Virological Methods, 1993) and Rasmussen et al. (Analytical Biochemistry, 1991).

The instant invention is drawn to a kit comprising polyriboadenylic acid (prA) and/or polydeoxyadenylic acid (pdA) bound to a solid surface, the kit further comprises RT-type assay components. The kit may also contain (does not require) a reference enzyme and a detection system.

Shao et al. teaches the use of a non-radioactive microtiter plate RT-assay in which the immobilized template polyriboadenylic acid (prA) is bound to the plate (see figure 1). The

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reference does not teach binding the poly (A) to the plate using methylimidazole in the binding buffer.

Ekstand et al. teaches the use of a non-radioactive microtiter plate RT-assay in which the immobilized template polyriboadenylic acid (prA) is bound to the plate (see page 97, template binding and enzyme assay). The reference does not teach binding the poly (A) to the plate using methylimidazole in the binding buffer.

Suzuki et al. teaches an RT assay in which the poly A was linked to microtiter plates using hydroxysulfosuccinimide and 1-ethyl-3-(3-hydroxysulfosuccinimide) carbodiimide hydrochloride. The reference teaches an RT assay using biotin-dUTP solution, TTP, KCL, Mg2Cl, Tris, pH 7.8, DTT oligo dT for the RT reaction. The HRP enzyme reaction was carried using TMB as the final color reactant (see page 191). The reference does not teach the use of an RNA inhibitor or the use of a polyamine, or the use of a stabilizing agent and the use of protective agents in the RT assay buffer. The reference does not teach binding the poly (A) to the plate using methylimidazole in the binding buffer.

Rasmussen et al. teaches the covalent immobilization of double stranded and single stranded DNA to polystyrene microwells on a CovaLink NH plate. The reference utilizes 10 mM 1-methylimidazole in the binding buffer and an incubation temperature of 50C for 5 hours. The reference also teaches using various concentrations of EDC and 1-methylimidazole (see page 140, column1 2nd paragraph). The reference does not disclose a reverse transcriptase assay.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the binding condition for the poly A or poly dA to the polystyrene based ELISA plate to obtain the maximum signal from the RT assay as set out in Shao et al. and

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Ekstand et al. Suzuki et al. utilizes Covalink plates from NUNC and the coupling agent EDC [1-ethy-3-(3-dimethylaminopropyl)-carbodiimide] in N-hydroxysulfosuccinimide to bind the poly A to the bottom of the plate. Rasmussen et al. utilizes the CovaLink NH plates in conjunction with the coupling agent EDC dissolved in 1-methylimidazole. Single stranded DNA has the similar structure to poly dA and poly A, therefore, one of ordinary skill in the art would have had a high expectation of success in applying the EDC coupling agent in 1-methylimidazole for the efficient directional binding to the bottom of the plate as taught by Rasmussen et al. The reference also uses the same carbodiimide condensing agent as suggests by the manufacturer of the CovaLink NH plates. Optimizing the conditions such as varying the 1-methylimidazole and condensing agent for binding the target onto the bottom of the plate would fall within the skill of the ordinary artisan and is suggest by Rasmussen et al. Therefore, based on what was known in the art the instant assay kit and methods are obvious over Shao et al., Ekstand et al. , Suzuki et al. and Rasmussen et al.

Conclusion


No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-746-3162.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


ULRIKE WINKLER, PH.D.
PATENT EXAMINER 9/30/03